Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

MICHAEL POSTAWKO, et al.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CASE NO. 2:16-cv-4219-NKL-P**
	)	
MISSOURI DEPARTMENT OF CORRECTIONS, *et al.*	)	
	)	
Defendants.	)	

DECLARATION OF DR. JERRY LOVELACE

I, DR. JERRY LOVELACE, pursuant to 28 U.S.C. § 1746, hereby make the following Declaration under penalty of perjury, declare that the statements made below are true, and state:

1. My name is Dr. Jerry Lovelace, M.D., PhD. I am over the age of nineteen (19) years and have personal knowledge of the information contained in this Declaration.

2. I am a physician licensed to practice medicine in Missouri, Tennessee, and Alabama. I am the Regional Medical Director ("RMD") for the State of Missouri for Corizon, LLC ("Corizon") and have served in this capacity since 2016.

3. Corizon is a limited liability corporation registered and in good standing with the State of Missouri. Corizon contracts with the State of Missouri to provide a defined scope of medical services to inmates in the custody of the Missouri Department of Corrections ("MDOC").

4. As the RMD, I am responsible for the approval and administration of the protocols (collectively, the "Missouri Policy") for the management and treatment of chronic hepatitis C ("HCV") under Corizon's contract with the MDOC. The Missouri Policy sets forth a detailed pathway for the screening and treatment of HCV The Missouri Policy includes the following pathways and guidelines: a) Initial HCV Chronic Care Clinic, dated December 19, 2018; b)

Follow-Up HCV Chronic Care Clinic, dated December 19, 2018; c) Hepatitis C: Nurse Chronic Care Clinic Protocol, dated December 28, 2016; d) Cirrhosis Pathway, dated December 19, 2018; e) Hepatitis C Treatment Pathway, dated December 19, 2018; and f) Considerations for Hepatitis Treatment Pathway, dated December 19, 2018. These protocols are attached hereto collectively as Exhibit A.

5. I have reviewed the Affidavit of Dr. Thomas Bredeman, dated February 28, 2017 (the "Bredeman Affidavit"). As Dr. Bredeman stated, HCV is a viral, blood-borne infectious disease. Acute HCV infection can occur within the first six (6) months of exposure to the HCV virus, while chronic HCV refers to a long-term infection.

6. The Bredeman Affidavit accurately reflected HCV treatment policies for inmates in MDOC custody at the time. Most of these policies have been updated since that time, as reflected above. The key change since the Bredeman Affidavit is that Corizon now uses four (4) different direct-acting antiviral ("DAA") drugs for HCV care (Vosevi, Epclusa, Mavyret and Zepatier). Medical providers prescribe these DAA drugs depending on the particular circumstances of each case. The current Missouri Policy also contains updated treatment considerations for Priority 1 patients, in a continuing effort to allow medical professionals to consider a broad range of factors in their treatment decisions.[1]

7. As discussed in the Bredeman Affidavit, the Missouri Policy is consistent with the Federal Bureau of Prisons' Clinical Guidance for the Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection (the "FBOP Guidelines"). Reflecting the fact that DAA therapy for HCV is rapidly changing, the FBOP updated its Guidelines multiple times between May 2014

[1] This declaration does not purport to update the medical conditions of the three Plaintiffs discussed in the Bredeman Affidavit: Michael Postawko, Christopher Baker, and Michael Jamerson.

and August 2018. The most recent version of the FBOP Guidelines, dated August 2018, is available at https://www.bop.gov/resources/pdfs/hcv_infection_20180906.pdf.

8. Consistent with the FBOP Guidelines, providers within the MDOC assign each inmate with chronic HCV a Priority Level of 1, 2, or 3. Priority 1 represents the highest priority for treatment, while Priority 3 represents the lowest priority.

9. I am also aware of the guidance for HCV promulgated by the American Association for the Study of Liver Disease (the "AASLD") and the Infectious Disease Society of America (the "IDSA"). This guidance is available at https://www.hcvguidelines.org/. Providers within the MDOC frequently consult this guidance in determining the appropriate course of treatment for particular inmates with HCV. While this guidance is a helpful resource for practitioners, I do not understand the guidance to represent the standard of care or otherwise provide any mandatory requirements with respect to HCV treatment.

10. The science surrounding DAA therapy continues to evolve. Several new DAA drugs have become available in recent years. Medical providers within MDOC facilities keep abreast of these new medications and prescribe them as appropriate. Between 2015 and 2019, providers within MDOC have prescribed DAA therapy for an increasing number of inmates each year. Approximately five (5) inmates completed DAA therapy in 2015. In 2016, approximately fourteen (14) inmates completed DAA therapy. That number increased to approximately nineteen (19) in 2017 and approximately fifty-one (51) in 2018. Through June 30, 2019, approximately fifty (50) inmates in MDOC custody completed DAA therapy. Approximately anther 150 inmates were receiving DAA therapy as of June 30, 2019. All of the inmates designated Priority 1, with the exception of those who only recently received that designation, completed or were receiving DAA therapy as of June 30, 2019.

11. I also am familiar with the potential costs associated with DAA therapy. DAA therapy for all inmates diagnosed with HCV currently in the custody of MDOC would cost approximately $90,000,000, which is roughly 68% of the total budget for medical and mental health services.[2] Such an expenditure on medically unnecessary therapy would severely impact the ability to provide other, potentially more urgent, medical care to inmates within MDOC.

I declare under penalty of perjury that the foregoing is true and correct. I understand that a false statement in this Declaration will subject me to penalties for perjury.

Executed on August 5, 2019

DR. JERRY LOVELACE

[2] This number is dependent on a number of factors, including but not limited to the specific genotype of HCV and specific type of DAA therapy required for each inmate, the timing of DAA therapy, and potential changes in the inmate population.

Exhibit A

TITLE:	Cirrhosis Pathway
Physician Approval/Date: Dr. Jerry Lovelace M.D	

(S) SUBJECTIVE:

_____ Y/N History of Hepatitis C
Date diagnosed:_____
_____ Y/N History of Hepatitis B
Date diagnosed:_____
_____ Y/N History of alcohol use
_____ Y/N History of metabolic syndrome/DM (non –alcoholic fatty liver disease)
_____ Y/N Symptoms: Fatigue, easy bruising, lower extremity edema, fever, weight loss, diarrhea, pruritus, increasing abdominal girth, hematemesis, confusion, or sleep disturbances (possibly indicating encephalopathy). List:_____
_____ Y/N Other causes of Cirrhosis; what: _____

(O) OBJECTIVE:

_____ Y/N Icterus or jaundice
_____ Y/N Ascites
_____ Y/N Peripheral edema
_____ Y/N Spider angiomata or spider telangiectasia
_____ Y/N Hepatomegaly
_____ Y/N Splenomegaly
_____ Y/N Asterixis
_____ Y/N Caput medusa
_____ Y/N Palmar erythema

Abdominal Exam: _____
Skin findings: _____
_____ Y/N Evidence of altered mood, confusion, inappropriate behavior, somnolence.
If yes list: _____

_____Y/N Labs Reviewed
Labs:

Date:	Results:
_____	_____ Albumin
	_____ AST

_____ ALT
_____ Creatinine
_____ eGFR
_____ Total bilirubin

Date: Results:

_____ _____ HGB
_____ Platelets
_____ _____ PT/INR

**For below calculations see: http://www.hepatitisc.uw.edu/page/clinical-calculators/apri

_____APRI Score
_____CTP Score
_____FIB-4 index

_____ Y/N Ultrasound results: _____
_____ Y/N EGD results: _____

_____ Y/N Hepatitis A immune or vaccination
_____ Y/N Hepatitis B immune or vaccination
_____ Y/N Pneumococcal vaccination: If yes; date: _____
_____ Y/N Potentially hepatotoxic drugs (esp. NSAIDS, Metformin if end stage): _____

_____ Y/N Other medical conditions: _____

(A) ASSESSMENT:

PRIORITIES FOR TREATMENT:

PRIORITY 1:

- **ADVANCED HEPATIC FIBROSIS/CIRRHOSIS, LIVER TRANSPLANT RECIPIENTS, HCC, COMORBID HEPATITIS C CONDITIONS, IMMUNOSUPPRESSANT MEDICATION, OFFENDERS ALREADY ON TREATMENT---REFER TO CONSIDERATION OF HEPATITIS C TREATMENT PATHWAY**

PRIORITY 2:

- **HIV OR HEPATITIS B CO-INFECTION, APRI >/=0.7-1.99, STAGE 2 FIBROSIS, DM, COMORBID LIVER DISEASE, eGFR </=59**

PRIORITY 3:

- **APRI <0.7, FIBROSIS </=STAGE 1**

_____ Y/N Compensated (Child A, CTP 5-6)
_____ Y/N Functionally compromised (Child B, CTP 7-9)
_____ Y/N Decompensated (Child C, CTP 10+)
_____ Y/N Hepatitis B
_____ Y/N Hepatitis C
_____ Y/N Other (Non-alcoholic fatty liver disease, hemochromatosis, autoimmune, cholangitis, alcoholic cirrhosis)
Specify: _____

(B) PLAN:

_____ Y/N Update problem list and M-score (M-score 3-4 if CTP >6, 5 if TCU care needed)

_____ Y/N Currently undergoing treatment for Hepatitis B or C
_____ Y/N Liver ultrasound every 6 months if APRI >2, CTP >6, FIB-4 index >3.25 or clinical signs of cirrhosis.
_____ Y/N EGD to screen for varices if evidence of functional compromise (CTP >6, portal hypertension noted on US, platelets <150,000 in Hepatitis C, or FIB-4 index >3.25)-every 2-3 years if compensated, 1-2 years if small varices and not on B-blocker, yearly if decompensated.
_____ Y/N If FIB-4 between 1.45-3.25, findings are indeterminate, consider Fibrosure test
_____ Y/N Non-selective beta-blocker (propranolol, nadolol) or carvedilol if evidence of varices in Child B or C (goal heart rate 55-60 unless refractory ascites)
_____Y/N Avoid NSAIDS, PPI, Metformin or reduce dosages of some medications (antibiotics, SSRI's) if decompensated or hepatorenal syndrome (add to allergy screen)
_____ Y/N Pneumococcal vaccine (PPSV23), provide pneumococcal vaccine initially. Revaccinate at age ≥65 if they were vaccinated ≥5 years previously and were aged <65 at the time of initial vaccination
_____ Y/N If patient is not already immune to HAV (known by positive HAV total AB) or already s/p vaccination, Hepatitis A Vaccine series 1 ml now then repeat in 6 months.
_____ Y/N If patient is not already immune to HBV or already S/P vaccination, Hepatitis B Vaccine series 1 ml now then repeat in 1 month then 6 months

_____ Y/N Ascites (spironolactone: furosemide at ratio of 100:40 up to 400:160/day-use by mouth in the morning; and Na+ restriction (2000mg/day) – avoid ACE, ARB, non-selective B-blockers if refractory)
_____ Y/N Encephalopathy – lactulose/rifaximin
_____ Y/N Antibiotic prophylaxis if high risk spontaneous bacterial peritonitis (prior episode SBP, variceal Hemorrhage, serum albumin <2). Treatment: Bactrim DS daily or Cipro 500mg daily
_____ Y/N Physician follow-up in 6 months if Child A or B (CTP>/=6-9)
_____ Y/N Obtain: CMP, CBC and PT/INR every 6 months if Child A or B (CTP>/=6-9)
_____ Y/N Physician follow-up in 3 months if CTP C (CTP >/=10)
_____ Y/N Chronic Care visit sooner; if yes, when:_____
_____ Y/N Obtain: CMP, CBC and PT/INR every 3 months if CTP C (CTP>/=10)
_____Y/N Patient counseled on immediate follow-up if symptoms of decompensation (increased abdominal girth, LE edema, hematemesis)

Candidate for treatment of Hepatitis C – complete labs for Hepatitis C treatment and notify RMD

TITLE:	Consideration of Hepatitis C Treatment
Physician Approval/Date: Dr. Jerry Lovelace, M.D.	

(S) SUBJECTIVE:

_____ Y/N Patient complains of HCV symptoms (N/V, abdominal pain, fatigue, jaundice)
If so; list: _____
_____ Y/N Patient complains of symptoms of cirrhosis (easy bruising, LE edema, increasing abdominal girth, hematemesis) If so; list: _____
Brief review of risks: _____

(O) OBJECTIVE:

_____ Y/N Advanced hepatic fibrosis/cirrhosis (confirmed by ultrasound, biopsy, esophageal varices, ascites, physical stigmata, APRI >2, FIB-4 >1.45, low albumin, AST/ALT Ratio >1)
_____ Y/N Liver transplant recipient
_____ Y/N HIV or Hepatitis B co-infection
_____ Y/N Comorbid medical condition associated with HCV, e.g. cryoglobulinemia, certain types of lymphomas, hematologic malignancies, porphyria cutanea tarda, vasculitis
_____ Y/N Newly incarcerated offender being treated at the time of incarceration
_____ Y/N On immunosuppressant therapy
_____ Y/N Hepatocellular carcinoma
_____ Y/N Diabetes mellitus
_____ Y/N Chronic kidney disease 3 or greater (eGFR </=59)
_____ Y/N Life expectancy >18 months
_____ Y/N Pregnant
_____ Y/N Co-morbid liver diseases (autoimmune hepatitis, hemochromatosis, steatohepatitis)

_____ Y/N HCV Antibodies positive: Date: _____
_____ Y/N Icterus or jaundice
_____ Y/N Ascites
_____ Y/N Peripheral edema
_____ Y/N Spider angiomata or spider telangiectasia
_____ Y/N Hepatomegaly
_____ Y/N Asterixis

Abdominal Exam: _____

Skin findings: _____
Physical findings of cirrhosis: _____

_____ Y/N Labs Reviewed

Labs:

Date:	Results:	
_____	_____	Albumin
	_____	AST
	_____	ALT
	_____	Total bilirubin
_____	_____	Platelets

APRI Score: _____ FIB-4: _____ CTP: _____
*****For APRI calculations see: http://www.hepatitisc.uw.edu/page/clinical-calculators/apri

Date:	Results:	
_____	_____	WBC
	_____	Hgb
	_____	MCV
	_____	ANC
_____	_____	Creatinine/eGFR
_____	_____	PT/INR
_____	_____	ANA

Date: _____ Results:
Iron: _____ TIBC: _____ % Iron Sat: _____ Ferritin: _____

Date:	Results:	
_____	_____	HIV
_____	_____	Pregnancy test (female)

Date: _____ Results:
Hepatitis B Surf Ag: _____ Hepatitis B Surf Ab: _____
Hepatitis B Core Ab: _____ Hepatitis A Total Ab: _____
Hepatitis B Delta x 1 (If Hepatitis B positive) _____

Date:	Results:	
_____	_____	Genotype (if known)
_____	_____	Viral load (if known)
_____	_____	Fibrosure test (if known)
_____	_____	Liver biopsy-stage

Mandatory Release Date:_____
Parole Date:_____

_____ Y/N HAV total antibodies positive or vaccine

_____ Y/N HBV surface antigen positive
_____ Y/N HBV surface antibody positive or vaccine
_____ Y/N Pneumococcal vaccine given: If yes; date: _____
_____ Y/N Is patient on any potentially hepatotoxic drugs: If yes; list: _____
Other medical conditions: _____

(A) ASSESSMENT:

Hepatitis C
PRIORITIES FOR TREATMENT:

PRIORITY 1
_____ Y/N ADVANCED HEPATIC FIBROSIS/CIRRHOSIS,
_____ Y/N LIVER TRANSPLANT RECIPIENTS
_____ Y/N HCC
_____ Y/N COMORBID HEPATITIS C CONDITIONS
_____ Y/N IMMUNOSUPPRESSANT MEDICATION
_____ Y/N OFFENDERS ALREADY ON TREATMENT

PRIORITY 2
_____ Y/N HIV CO-INFECTION
_____ Y/N HEPATITIS B CO-INFECTION
_____ Y/N APRI >/=0.7
_____ Y/N STAGE 2 FIBROSIS
_____ Y/N DM
_____ Y/N COMORBID LIVER DISEASE
_____ e-GFR </=59

If cirrhotic:
_____ Y/N Compensated (Child A, CTP 5-6)
_____ Y/N Functionally compromised (Child B, CTP 7-9)
_____ Y/N Decompensated (Child C, CTP 10+)
_____ Y/N Other (non-alcoholic fatty liver disease, hemochromatosis, autoimmune, cholangitis, alcoholic cirrhosis)
Specify: _____

(P) PLAN:

Consideration of Treatment/Priority 1
_____ Y/N Patient counseled by physician on treatment and side effects
_____ Y/N Consent for treatment reviewed and signed
_____ Y/N No consideration of treatment or refusal of treatment-return to the Follow-up HCV Chronic Care Clinic
_____ Y/N Patient's current Hepatitis C status was discussed
_____ Y/N Obtain any labs not already completed under objective (ferritin, % Iron sat, TIBC, ANA, Hepatitis C viral load, CBC, CMP, PT/INR, Hepatitis Delta if Hepatitis B Positive)
_____ Y/N Evidence of current/prior medication adherence compliance? If yes; list: _____
_____ Y/N Review of recent health risk exposures (new tattoos, substance use or possession)
List any concerns: _____

Obtain the following AFTER approved for the initiation of treatment:

_____ Y/N Obtain urine toxicology
_____ Y/N Obtain TSH, ANC if Ribavirin to be used (Regional Office will advise)
_____ Y/N Obtain HCV Genotype-if HCV RNA PCR shows virus, <90 days before treatment to start
_____ Y/N Obtain fundoscopic exam if retinopathy and Ribavirin to be used
_____ Y/N Obtain a urine pregnancy test on females
_____ Y/N EKG (if pre-existing cardiac history and Ribavirin)
_____ Y/N HIV Positive and well controlled HIV disease, consult HIV Expert for treatment recommendations
_____ Y/N Educate on birth defects and need for 2 forms of birth control up to 6 months post treatment if Ribavirin indicated.

TITLE:	**Follow-up HCV Chronic Care Clinic**
Physician Approval/Date: Dr. Jerry Lovelace, M.D.	

(S) SUBJECTIVE:

_____ Y/N Patient complains of HCV symptoms (N/V, abdominal pain, fatigue, jaundice) If so;
List:: _____

_____Y/N Patient complains of symptoms of cirrhosis (easy bruising, LE edema, increasing abdominal girth, hematemesis)
List: _____

Brief review of risks: _____

(O) OBJECTIVE:

_____ Y/N Advanced hepatic fibrosis/cirrhosis (confirmed by ultrasound, biopsy, esophageal varices , ascites, physical stigmata, APRI >2, FIB-4 >3.25, low albumin, AST/ALT Ratio >1)
_____ Y/N Liver transplant recipient
_____ Y/N HIV or Hepatitis B co-infection
_____ Y/N Comorbid medical condition associated with HCV, e.g. cryoglobulinemia, certain types of lymphomas, Hematologic malignancies, porphyria cutanea tarda, vasculitis
_____ Y/N Newly incarcerated offender being treated at the time of incarceration
_____ Y/N On immunosuppressant therapy
_____ Y/N Hepatocellular carcinoma
_____ Y/N Diabetes mellitus
_____ Y/N Chronic kidney disease 3 or greater (eGFR </=59)
_____ Y/N Life expectancy >18 months
_____ Y/N Pregnant
_____ Y/N Co-morbid liver diseases (autoimmune hepatitis, hemochromatosis, steatohepatitis)

_____ Y/N HCV Antibodies positive: Date:_____
_____ Y/N Icterus or jaundice
_____ Y/N Ascites
_____ Y/N Peripheral edema
_____ Y/N Spider angiomata or spider telangiectasia
_____ Y/N Hepatomegaly
_____ Y/N Asterixis

Abdominal Exam: _____

Skin findings: _____
Physical findings of cirrhosis: _____

_____Y/N Labs Reviewed
Labs:

Date:	Previous Results:	Date:	Current Results:
_____	_____ Albumin	_____	_____ Albumin
	_____ AST		_____ AST
	_____ ALT		_____ ALT
	_____ Total bilirubin		_____ Total Bilirubin
Date:			
_____	_____ Platelets	_____	_____ Platelets

_____APRI Score _____ FIB-4 Score _____ APRI Score _____ FIB-4 Score
****** For APRI calculations see: http://www.hepatitisc.uw.edu/page/clinical-calculators/apri

Date:	Results:
_____	_____ Genotype (if known)
_____	_____ Viral load (if known)

Liver biopsy-stage: _____Date: _____

Treatment Completion Date:_____

_____ Y/N HAV total antibodies positive or vaccine
_____ Y/N HBV surface antigen positive
_____ Y/N HBV surface antibody positive or vaccine
_____ Y/N Hepatitis B Core Ab positive
_____ Y/N Is patient on any potentially hepatotoxic drugs
If yes, list: _____
Other medical conditions: _____

(A) ASSESSMENT:

PRIORITIES FOR TREATMENT:

PRIORITY 1

- **ADVANCED HEPATIC FIBROSIS/CIRRHOSIS, LIVER TRANSPLANT RECIPIENTS, HCC, COMORBID HEPATITIS C CONDITIONS, IMMUNOSUPPRESSANT MEDICATION, OFFENDERS ALREADY ON TREATMENT---REFER TO CONSIDERATION OF HEPATITIS C TREATMENT PATHWAY**

PRIORITY 2

- **HIV OR HEPATITIS B CO-INFECTION, APRI >/=0.7-1.99, STAGE 2 FIBROSIS, DM, COMORBID LIVER DISEASE, e-GFR </=59**

PRIORITY 3

- **APRI <0.7, FIBROSIS </=STAGE 1**

_____ Y/N Improved
_____ Y/N Stable
_____ Y/N Worsened

_____ Y/N Evidence of cirrhosis (physical signs of cirrhosis, APRI >/=2, CTP >6, Hep C with plt. <150,000, FIB-4 >3.25, low albumin, AST/ALT Ratio >1)

_____ Y/N Resolved (no detectable HCV RNA 6-12 months post treatment or if untreated no detectable viral load x 1)
Date and result of SVL: _____
_____ Y/N Failed Treatment

Chronic Hepatitis C
_____ Y/N Patient is priority 1
_____ Y/N Patient is priority 2 or 3
_____ Y/N Patient declines therapy (signed refusal of treatment and documented)
_____ Y/N Failed prior treatment
____ Y/N Dual Therapy
____ Y/N Triple Therapy
_____ Y/N Does have enough time remaining in prison to complete treatment-Release Date: _____
_____ Y/N Other medical contraindication (life expectancy <18 mo, pregnancy, other) If yes, list:_____
_____ Y/N Demonstrates on-going or recent high risk behavior – drug use, new tattoos, etc.

(P) PLAN:

Priority 1:
_____ Y/N if evidence of cirrhosis, reassess every 3-6 months in CY clinic using the Cirrhosis Pathway

_____ Y/N APRI >2 on two occasions and AST/ALT Ratio >1
_____ Y/N Stigmata of cirrhosis on physical exam (esp. spider angiomatas)
_____ Y/N Evidence of ascites, esophageal varices
_____ Y/N FIB-4 >3.25
_____ Y/N FIB-4 between 1.45-3.25, findings are indeterminate, consider Fibrosure test
_____ Y/N Low albumin

Plan for Priority 2 or 3
_____ Y/N Physician CY Chronic Care appointment every 6 months if APRI >0.7
_____ Y/N Chronic Care appointment sooner, if yes; when: _____
_____ Y/N Physician CY Chronic Care appointment every 12 months if APRI <0.7, with nursing clinic at 6 months
_____ Y/N CMP, CBC (with differential & platelets) every 6 months if APRI >0.7
_____ Y/N CMP, CBC (with differential & platelets) every 12 months if APRI <0.7, with nursing clinic at 6 months
_____ Y/N If hepatitis B positive, must be on treatment for Hepatitis B with negative viral load before referring for treatment
_____ Y/N Evaluate APRI and FIB-4 scores with each lab draw
_____ Y/N M-Score and Duty Status appropriate
_____ Y/N If patient is not already immune to HAV (known by positive HAV total AB) or already s/p vaccination, Hepatitis A Vaccine 1 ml now then repeat in 6 months.
_____ Y/N If patient is not already immune to HBV or already S/P vaccination, Hepatitis B Vaccine series 1 ml now then repeat in 1 month then 6 months
_____ Y/N Patient's current Hepatitis C status was discussed
_____ Y/N Consider HCV RNA if LFT's are within normal limits for 2 years
_____ Y/N Remove from clinic if undetectable HCV RNA

TITLE:	Hepatitis C Treatment
Physician Approval/Date: Dr. Jerry Lovelace, M.D.	

(S) SUBJECTIVE:

_____ Y/N Side effects (common-HA, fatigue, weakness; less common insomnia, N/V, dizziness, depression, cough)
List: _____
_____Y/N Side effects from ribavirin (flu-like symptoms, fatigue, neuro-psychiatric, hematologic,,worsening cardiac symptoms)

(O) OBJECTIVE:

Date of diagnosis of Hepatitis C: _____
Week of medication: _____
_____ Y/N Ribavirin - Decision to use ribavirin will be made by the Regional Office.

Physical Exam:
Heart: _____
Abdomen: _____
Skin: _____

_____Y/N Labs Reviewed
Date: _____
Genotype: _____
HCV RNA pre-treatment: _____
HCV RNA at 4 weeks (repeat at 6 weeks if still detectable at 4 weeks) _____
HCV RNA at 6 weeks (only if still detectable at 4 weeks) _____
Date: _____

_____Albumin
_____AST
_____ALT
_____Creatinine
_____Total bilirubin
_____eGFR (if <30 Ledipasvir and Sofosbuvir contra-indicated)

If ribavirin
_____Hgb
_____Platelets
_____ANC
_____TSH

_____APRI Score
_____CTP Score
_____FIB-4 Score

_____ Y/N Hepatitis A immune or vaccination

_____ Y/N Hepatitis B immune or vaccination
_____ Y/N Potential drug interactions: (esp. PPI, H2-antagonist, antiacids, tenofovir, oxcarbazepine, rosuvastatin, amiodarone for ledipasavir/sofosbuvir: azathioprine, didanosine, zidovudine for ribavirin)
If yes, list: _____
_____ Y/N Underlying retinopathy
Other medical conditions: _____

(A) ASSESSMENT:

_____ Y/N Cirrhosis
_____ Y/N Compensated (Child Pugh A or B)
_____ Y/N Decompensated (Child Pugh C)
_____ Y/N Hepatitis C
_____ Y/N Treatment naïve
_____ Y/N Treatment experienced
Genotype: _____

_____ Y/N Improved
_____ Y/N Stable
_____ Y/N Worsened
_____ Y/N Successful Treatment (6-12 month post treatment with undetectable viral load)
Date and result of SVL: _____
_____ Y/N Failed Treatment
_____ Y/N Treatment with antiviral:
List: _____
_____ Y/N Treatment includes ribavirin (**Hemolytic anemia is the primary clinical toxicity of oral therapy; anemia associated with ribavirin may worsen underlying cardiac disease and lead to fatal and nonfatal myocardial infarctions. Avoid use in patients with significant/unstable cardiac disease)**

(P) PLAN:

If antiviral alone:
_____ Y/N Treatment with: List: _____
_____ Y/N CMP & CBC per committee recommendations
_____ Y/N More frequent if concerning trends.
_____ Y/N Provider visit monthly

If ribavirin included:

_____ Y/N CMP and CBC per committee recommendations
_____Y/N More frequent if concerning trends.
_____ Y/N TSH at baseline and week 12
_____ Y/N Preexisting ophthalmologic disorders (eg, diabetic or hypertensive retinopathy) require periodic optometry follow-up
_____Y/N Pre-existing psychiatric disorder with worsening—refer to psychiatry
_____Y/N Provider visit monthly

Dosing, for period prescribed by Regional Office (will vary from 12-24 weeks)

_____ Y/N <75 kg: 1,000 mg daily in 2 divided doses
_____ Y/N ≥75 kg: 1,200 mg daily in 2 divided doses
Dosing Modification based on hemoglobin level:
_____ Y/N Hb >/= 10 no change
_____ Y/N Hb 8.5-9.9 reduce dose to 800mg total daily dose
_____ Y/N Hb <8.5 hold ribavirin for 1 week then resume at 600mg total daily dose
_____ Y/N Platelets <25,000 stop all meds

For all patients:

_____ Y/N Hepatitis C RNA (viral load) at week 4
_____ Y/N Hepatitis C RNA (viral load) at week 6 if detectable at week 4
_____ Y/N Hepatitis C RNA at 12 weeks post treatment completion
_____ Y/N Hepatitis C RNA (viral load) at 6-12 months post treatment for SVR

_____ Y/N D/C treatment if ALT >10 x baseline or if hyperbilirubinemia or if accompanied by symptoms of liver failure
_____ Y/N D/C treatment if the 6 week viral load has increased >1 log

_____Y/N D/C treatment pathway once treatment completed
_____Y/N D/C CY clinic if 6-12 mo post treatment viral load (SVR) assured
_____Y/N If evidence of cirrhosis and SVR assured, then continue to follow in Internal Medicine Clinic Instead (using the Cirrhosis Pathway)

TITLE:	Initial HCV Chronic Care Clinic
Physician Approval/Date: Dr. Jerry Lovelace, M.D.	

(S) SUBJECTIVE:

Do you know when you acquired this_____?
Risk Factors:
_____ Y/N IV or intranasal drug use
Date first used:_____
Date last used:_____
_____ Y/N First tattoo
Date
Prison/jail?_____
_____ Y/N Dialysis
_____ Y/N Transfusion/organ transplant before 1992
_____ Y/N Alcohol history
Date first used:_____
Date last used:_____

_____ Y/N Patient complains of HCV symptoms – (nausea/vomiting, abdominal pain, fatigue, jaundice)
If so list: _____
_____Y/N Patient complains of symptoms of cirrhosis (easy bruising, LE edema, increasing abdominal girth, hematemesis)
List: _____
_____ Y/N History of treatment for hepatitis C?
Dates:_____
Agents used:_____
_____ Y/N Viral clearance

(O) OBJECTIVE:

_____ Y/N Advanced hepatic fibrosis/cirrhosis (confirmed by ultrasound, biopsy, esophageal varices, ascites, physical stigmata, APRI >2, FIB-4 >3.25, low albumin, AST/ALT Ratio >1)
_____ Y/N Liver transplant recipient
_____ Y/N HIV or Hepatitis B co-infection
_____ Y/N Comorbid medical condition associated with HCV, e.g. cryoglobulinemia and certain types of lymphomas, Hematologic malignancies, porphyria cutanea tarda, vasculitis
_____ Y/N Newly incarcerated offender being treated at the time of incarceration

_____ Y/N On immunosuppressant therapy
_____ Y/N Hepatocellular carcinoma
_____ Y/N Diabetes mellitus
_____ Y/N Chronic kidney disease 3 or greater (eGFR </=59)
_____ Y/N Life expectancy >18 months
_____ Y/N Pregnant
_____ Y/N Co-morbid liver diseases (autoimmune hepatitis, hemochromatosis, steatohepatitis)

_____ Y/N HCV Antibodies positive: Date:_____
_____ Y/N Icterus or jaundice
_____ Y/N Ascites
_____ Y/N Peripheral edema
_____ Y/N Spider angiomata or spider telangiectasia
_____ Y/N Hepatomegaly
_____ Y/N Asterixis
Abdominal Exam: _____
Skin findings: _____
Physical findings of cirrhosis: _____
_____Y/N Labs Reviewed
Labs:

Date:	Results:
_____	_____ Albumin
	_____ AST
	_____ ALT
	_____ Total bilirubin
_____	_____ Platelets

_____ APRI Score _____ FIB-4 Score
****** For APRI calculations see: http://www.hepatitisc.uw.edu/page/clinical-calculators/apri

Date:	Results:
_____	_____ Genotype (if known)
_____	_____ Viral load (if known)
_____	_____ Liver biopsy-stage:
_____	_____ Fibrosure test

_____ Y/N HAV total antibodies positive or vaccine
_____ Y/N HBV surface antigen positive/chronic hep B
_____ Y/N HBV surface antibody positive or vaccine
_____ Y/N Hepatitis B Core Ab positive
_____ Y/N Is patient on any potentially hepatotoxic drugs
If yes, list: _____
Other medical conditions: _____

Other Concerns

_____ Y/N eGFR <30:_____
_____ Y/N HIV Result _____ Date: _____
(If HIV+ consult HIV Expert for recommendations. HIV must be controlled before beginning therapy)
_____ Y/N Chronic Hepatitis B

(A) ASSESSMENT:

PRIORITIES FOR TREATMENT:

PRIORITY 1

- **ADVANCED HEPATIC FIBROSIS/CIRRHOSIS, LIVER TRANSPLANT RECIPIENTS, HCC, COMORBID HEPATITIS C CONDITIONS, IMMUNOSUPPRESSANT MEDICATION, OFFENDERS ALREADY ON TREATMENT---REFER TO CONSIDERATION OF HEPATITIS C TREATMENT PATHWAY**

PRIORITY 2

- **HIV OR HEPATITIS B CO-INFECTION, APRI >/=0.7-1.99, STAGE 2 FIBROSIS, DM, COMORBID LIVER DISEASE, e-GFR </=59**

PRIORITY 3

- **APRI <0.7, FIBROSIS </=STAGE 1**

_____ New enrollee
_____ Improved
_____ Stable
_____ Worsened
_____ Evidence of Cirrhosis (physical signs of cirrhosis, APRI >/=2, CTP >6, Hep C with plt <150,000, FIB-4 >3.25, low albumin, AST/ALT Ratio >1)

_____ Y/N Resolved (no detectable HCV RNA 6-12 months post treatment or if untreated no detectable viral load x 1)

Chronic Hepatitis C
_____ Y/N Patient is priority 1
_____ Y/N Patient is priority 2 or 3
_____ Y/N Patient declines therapy (signed refusal of treatment and documented)
_____ Y/N Failed prior treatment
____ Y/N Dual Therapy
____ Y/N Triple Therapy
_____ Y/N Does have enough time remaining in prison to complete treatment—release date:_____
_____ Y/N Other medical contraindication (life expectancy <18mo, pregnancy, other). If yes, list:_____
_____ Y/N Demonstrates on-going or recent high risk behavior – drug use, new tattoos, etc.

(P) PLAN:

Priority 1
_____ Y/N If evidence of cirrhosis, reassess every 3-6 months in CY clinic using the Cirrhosis Pathway

_____ Y/N APRI >2 on two occasions and AST/ALT Ratio >1
_____ Y/N Stigmata of cirrhosis on physical exam (esp. spider angiomatas)
_____ Y/N Evidence of ascites, esophageal varices
_____ Y/N FIB-4 >3.25
_____ Y/N FIB-4 between 1.45-3.25, findings are indeterminate, consider Fibrosure test
_____ Y/N Low albumin

Plan for Priority 2 or 3

_____ Y/N Physician CY Chronic Care appointment every 6 months if APRI >0.7, use the Follow-up HCV Chronic Care
Clinical Pathway
_____ Y/N Chronic Care appointment sooner, if yes; when: _____
_____ Y/N Physician CY Chronic Care appointment every 12 months if APRI <0.7, use the Follow-up HCV Chronic Care Clinical Pathway, with nursing clinic at 6 months
_____ Y/N CMP, CBC (with differential & platelets) every 6 months if APRI >0.7
_____ Y/N CMP, CBC (with differential & platelets) every 12 months if APRI <0.7, with nursing clinic every 6 months
_____ Y/N If hepatitis B positive, must be on treatment for Hepatitis B with negative viral load before referring for treatment
_____ Y/N Evaluate APRI and FIB-4 scores with each lab draw
_____ Y/N M-Score and Duty Status appropriate
_____ Y/N If patient is not already immune to HAV (known by positive HAV total AB) or already s/p vaccination, Hepatitis A Vaccine 1 ml now then repeat in 6 months.
_____ Y/N If patient is not already immune to HBV or already S/P vaccination, Hepatitis B Vaccine series 1 ml now then repeat in 1 month then 6 months
_____ Y/N Consider HCV RNA if LFT's within normal limits for 2 years
_____ Y/N Remove from clinic if HCV RNA undetectable
_____ Y/N Patient's current Hepatitis C status was discussed

TITLE:	Hepatitis C: Nurse Chronic Care Protocol
Physician Approval/Date: Dr. Thomas Bredeman, D.O.	

(S) SUBJECTIVE:

_____ (Y/N) RUQ pain
_____ (Y/N) Jaundice
_____ (Y/N) Lethargy/fatigue
_____ (Y/N) Disorientation
_____ (Y/N) Peripheral edema
_____ (Y/N) Chronic nausea and vomiting/vomiting blood
_____ (Y/N) Easy bruising

Other complaints: _____

(O) OBJECTIVE:

_____ (Y/N) Received Hepatitis A series
Date completed series: _____
_____ (Y/N) Received Hepatitis B series
Date completed series: _____
_____ (Y/N) Jaundice (skin or sclera)
_____ (Y/N) Petechiae
_____ (Y/N) Ascities present
_____ (Y/N) Abnormal abdominal exam, such as; right upper quadrant tenderness, distention
_____ (Y/N) Lower extremity edema

(A) ASSESSMENT: **Hepatitis C Chronic Care Clinic**

(P) PLAN:

_____ (Y/N) Unstable or concerns, contact provider for lab orders and earlier follow-up

Patient Education
_____ (Y/N) Healthy eating especially avoiding fatty foods
_____ (Y/N) Fluid intake 8-10 8-ounce cups of water per day
_____ (Y/N) Stop smoking
_____ (Y/N) Exercise
_____ (Y/N) Avoid more than 6 regular strength Tylenol in a day
_____ (Y/N) Avoid IV drug, tattooing, body piercing or having sex with other offenders
_____ (Y/N) Avoid sharing personal items that might have blood on them such as

toothbrushes, dental appliances, nail-grooming equipment or razors.

_____ (Y/N) Cover cuts and skin sores to keep blood from contacting other persons

_____ (Y/N) For the remainder of your life, do not drink alcohol at all, and speak to a physician prior to taking any new medications, including over-the-counter medications such as Ibuprofen and Aleve and herbal remedies, that may damage your liver.

_____ (Y/N) Upon release do not donate blood, semen, body organs or other tissue.

_____ (Y/N) Upon release seek medical attention so that you receive appropriate monitoring and treatment of your condition.

_____ (Y/N) Other: _____